UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,184	12/19/2001	Chad Cori Huval	1932.1064-033	8481

21005 7590 09/19/2006

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,184	HUVAL ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Response to Arguments

Applicant's arguments with respect to claims 2-3 and 8-10 have been considered but are moot in view of the new rejection necessitated by applicant's amendment.

The 103(a) rejection of the prior office action is withdrawn due to applicant's amendment of the claims and addition of two new claims not previously rejected.

The applicant's have brought to the examiner's attention that US Patent No. 6203785 was commonly owned with the present application at the time of filing and thus does not constitute prior art under 103(c). Thus '785 is no longer relied upon as prior art.

The applicant's have supplied a terminal disclaimer which has been approved. Thus the double patenting rejection of the last office action is overcome. Several other ODP issues have been uncovered and are detailed below.

Double Patenting

Claims 2-3 and 8-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6 and 10-12 of U.S. Patent No. 6083497. Although the conflicting claims are not identical, they are not patentably distinct from each other because present claim 2 is drawn to "a pharmaceutical composition comprising a unit dosage form of a polydiallylamine homopolymer, aid homopolymer characterized in that the polymer is free of alkylated amine monomers,

and a pharmaceutically acceptable carrier, wherein said homopolymer is cross linked by means of a multifunctional cross linking agent, and said cross linking agent is present in an amount from about 2.5-20% by weight, based upon the combined weight of monomer and cross linking agent." Present claim 3 further limits claim 2 by "...wherein the polymer is cross linked using epichlorohydrin." Present claim 8 is drawn to "a pharmaceutical composition comprising a unit dosage form of a polydiallylamine homopolymer, aid homopolymer characterized in that the polymer is free of alkylated amine monomers, and a pharmaceutically acceptable carrier, wherein said homopolymer is cross linked by means of a multifunctional cross linking agent, and said cross linking agent is present in an amount from about 2.5-20% by weight, based upon the combined weight of monomer and cross linking agent, wherein the unit dosage form is a capsule." Present claim 9 further limits claim 2 by "...wherein the polydiallylamine homopolymer is in the free base form". Present claim 10 limits claim 2 by "...wherein the polydiallylamine homopolymer is a salt or partial salt". Claims 1-4, 6, and 10-12 of US patent No. 6083497 are detailed below:

Claim 1. A method for removing bile salts from a patient comprising administering to said patient a therapeutically effective amount of a polydiallylamine polymer, said polymer characterized in that the polymer is free of alkylated amine monomers.

Claim 2. The method of claim 1 wherein said polymer is cross linked by means of a multifunctional cross linking agent, said agent being present in an amount from about 0.5-50% by weight, based upon the combined weight of monomer and cross linking agent.

Claim 3. The method of claim 2 wherein said cross linking agent is present in an amount from about 2.5-20% by weight, based upon the combined weight of monomer and cross linking agent.

Claim 4. The method of claim 2 wherein said cross linking agent comprises epichlorohydrin.

Claim 6. The method of claim 1 wherein the polymer is a homopolymer.

Claim 10. A method of removing bile salts from a patient comprising administering to said patient a therapeutically effective amount of a polydiallylamine polymer wherein the polydiallylamine polymer is characterized by monomeric units of the formulae: I and II or a combination thereof and salts thereof.

Claim 11. The method of claim 10 wherein the monomeric units are in the free base form.

Claim 12. The method of claim 10 wherein the monomeric units are a salt or partial salt.

While the '497 claims are drawn to methods and the present claims are drawn to compositions the claimed methods of the issued patent utilize the same compounds with the same cross linking agents in the same amounts as the currently claimed compositions and thus it would be obvious to claim the compositions utilized in the issued method claims. As these are continuation-in-part and/or continuations and not divisionals of each other, obviousness double patenting is appropriate.

Claims 2-3, 6 and 8-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-17 and 19 of U.S. Patent No. 6264938. Although the conflicting claims are not identical, they are not patentably distinct from each other because present claim 2 is drawn to "a pharmaceutical composition comprising a unit dosage form of a polydiallylamine homopolymer, aid homopolymer characterized in that the polymer is free of alkylated amine monomers, and a pharmaceutically acceptable carrier, wherein said homopolymer is cross linked by means of a multifunctional cross linking agent, and said cross linking agent is present in an amount from about 2.5-20% by weight, based upon the combined weight of monomer and cross linking agent." Present claim 3 further limits claim 2 by "...wherein the polymer is cross linked using epichlorohydrin." Present claim 8 is drawn to "a pharmaceutical composition comprising a unit dosage form of a polydiallylamine homopolymer, aid homopolymer characterized in that the polymer is free of alkylated amine monomers, and a pharmaceutically acceptable carrier, wherein said homopolymer is cross linked by means of a multifunctional cross linking agent, and said cross linking agent is present in an amount from about 2.5-20% by weight, based upon the combined weight of monomer and cross linking agent, wherein the unit dosage form is a capsule." Present claim 9 further limits claim 2 by "...wherein the polydiallylamine homopolymer is in the free base form". Present claim 10 limits claim 2 by "...wherein the polydiallylamine homopolymer is a salt or partial salt". Claims 12-17 and 19 of US patent No. 6264938 are detailed below:

Claim 12. A pharmaceutical composition comprising:

a) a first amount of an unsubstituted polydiallylamine polymer;

b) a second amount of an HMG CoA reductase inhibitor wherein said first and second amounts together comprise an effective amount; and

c) optionally, a pharmaceutically acceptable carrier.

Claim 13. The composition of claim 12 wherein the HMG CoA reductase inhibitor is selected from the group consisting of: atorvastatin, lovastatin, fluvastatin, pravastatin, simvastatin and mevastatin.

Claim 14. The composition of claim 12 wherein the unsubstituted polydiallylamine is characterized by one or more monomeric units of the formulae: I II

or a combination thereof and salts thereof.

Claim 15. The composition of claim 12 wherein said polymer is cross linked by means of a multifunctional cross linking agent, said agent being present in an amount from about 0.5-50% by weight, based upon the combined weight of monomer and cross linking agent.

Claim 16. The composition of claim 15 wherein said cross linking agent is present in an amount from about 2.5-20% by weight, based upon the combined weight of monomer and cross linking agent.

Claim 17. The composition of claim 15 wherein said cross linking agent comprises epichlorohydrin.

Claim 19. The composition of claim 12 wherein the polymer is a homopolymer.

The claims of '938 comprise a composition containing an unsubstituted diallylamine, an HMG CoA reductase inhibitor and optionally a pharmaceutically acceptable carrier. The currently claimed composition is a broader version of the '938 claims in that the current claims are drawn to a pharmaceutical composition comprising a unit dosage form of a polydiallylamine homopolymer. The diallylamine homopolymers are identical in identical percentages with identical cross linking agents. It would have been obvious that the current claims encompass the addition of any second agent as the current claim language is open and does not exclude the addition of any other active ingredient.

Claims 2-3, 6 and 10-12 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6 and 10-12 of U.S. Patent No. 6248318. Although the conflicting claims are not identical, they are not patentably distinct from each other because present claim 2 is drawn to "a pharmaceutical composition comprising a unit dosage form of a polydiallylamine homopolymer, aid homopolymer characterized in that the polymer is free of alkylated amine monomers, and a pharmaceutically acceptable carrier, wherein said homopolymer is cross linked by means of a multifunctional cross linking agent, and said cross linking agent is present in an amount from about 2.5-20% by weight, based upon the combined weight of monomer and cross linking agent." Present claim 3 further limits claim 2 by "...wherein the polymer is cross linked using epichlorohydrin." Present claim 8 is drawn to "a pharmaceutical composition comprising a unit dosage form of a polydiallylamine

homopolymer, aid homopolymer characterized in that the polymer is free of alkylated amine monomers, and a pharmaceutically acceptable carrier, wherein said homopolymer is cross linked by means of a multifunctional cross linking agent, and said cross linking agent is present in an amount from about 2.5-20% by weight, based upon the combined weight of monomer and cross linking agent, wherein the unit dosage form is a capsule." Present claim 9 further limits claim 2 by "...wherein the polydiallylamine homopolymer is in the free base form". Present claim 10 limits claim 2 by "...wherein the polydiallylamine homopolymer is a salt or partial salt". Claims 1-4, 6, and 10-12 of US patent No. 6248318 are detailed below:

Claim 1. A method for treating hypercholesterolremia in a patient administering to the gastrointestinal tract of said patient a therapeutically effective amount of a polydiallylamine polymer, said polymer characterized in that the polymer is free of alkylated amine monomers.

Claim 2. The method of claim 1 wherein said polymer is cross linked by means of a multifunctional cross linking agent, said agent being present in an amount from about 0.5-50% by weight, based upon the combined weight of monomer and cross linking agent.

Claim 3. The method of claim 2 wherein said cross linking agent is present in an amount from about 2.5-20% by weight, based upon the combined weight of monomer and cross linking agent.

Claim 4. The method of claim 2 wherein said cross linking agent comprises epichlorohydrin.

Claim 6. The method of claim 1 wherein the polymer is a homopolymer.

Claim 10. A method for treating hypercholesterolremia in a patient administering to the gastrointestinal tract of said patient a therapeutically effective amount of a polydiallylamine polymer wherein the polydiallylamine polymer is characterized by monomeric units of the formulae: I and II or a combination thereof and salts thereof.

Claim 11. The method of claim 10 wherein the monomeric units are in the free base form.

Claim 12. The method of claim 10 wherein the monomeric units are a salt or partial salt.

While the '318 claims are drawn to methods and the present claims are drawn to compositions the claimed methods of the issued patent utilize the same compounds with the same cross linking agents in the same amounts as the currently claimed compositions and thus it would be obvious to claim the compositions utilized in the issued method claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keim et al. (US Patent No. 3700623).

Keim et al. teach, in col. 1 lines 20-55, water-soluble resinous reaction products of a polymer of a diallylamine and an epihalohydrin such as epichlorohydrin. The resins are fast curing, water-soluble, and efficient. In example 5, 5g of diallyl amine monomer is reacted with 1g of epichlorohydrin cross-linking agent giving a 20% by weight amount of cross-linking agent. In example 6 the polymer to cross-linking agent percentage is 15.9%. In column 2 lines 63-70, Keim et al. teaches that the polymers can be homopolymers or copolymers and can exists as the salts or freebase of the final amines. Keim et al. teach, in col. 3 lines50-70, that the resinous products are soluble in water and the pH of the solutions can be adjusted to 6 or 5 by addition of hydrochloric, sulfuric, phosphoric, and acetic acids.

Keim et al. does not explicitly teach the resin to be used in pharmaceutical compositions.

One of ordinary skill in the art at the time the invention was made would recognize that Keim et al's. homopolymer being water soluble (water being a pharmaceutically acceptable carrier) and being neutralized by pharmaceutically acceptable acids would result in a composition suitable for pharmaceutical formulation. As the homopolymers Keim et al. detail are exactly the polymers currently claimed, the properties the applicant's have discovered are inherently present in Keim et al's. homopolymers. One would be motivated to use Keim's homopolymers in pharmaceutical compositions due to their water-solubility, cationic nature, fast curing and efficient synthesis.

"Products of identical chemical composition can not have mutually exclusive properties. " A chemical composition and its properties are inseparable. Therefore, if

the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW